

REMARKS

Applicant has amended the specification to include SEQ ID NOs in the Brief Description of the Drawings for the sequences depicted in Figs. 3, 7 and 11. Applicant also has amended the specification to remove browser-executable code as required by the Examiner. This has been accomplished by deleting "http://" and/or "www.", thereby leaving only non-executable website URLs.

Applicant has amended the claims to cancel non-elected claim 9 and to clarify the claim language. Applicant also has amended claim 79 to include SEQ ID NO:5 as a peptide that is used in the claimed method. Support for this amendment is found on page 52, line 6-7. No new matter has been added.

Objection to the Specification

The Examiner objected to the specification on the basis that it contained executable hyperlinks or other browser executable code. As noted above, Applicant has amended the relevant paragraphs to remove "http://" and/or "www.". The resulting text is not executable.

Applicant also amended the specification to insert sequence identifiers for peptides disclosed in the figure descriptions, as required by the Examiner.

Reconsideration is requested in view of the amendment of the specification.

Rejections Under 35 U.S.C. § 112, First Paragraph

Written Description Rejection

The Examiner rejected claims 8 and 79-85 as lacking an adequate written description. According to the Examiner, the basis for the rejection is that the specification does not convey to one of ordinary skill in the art that Applicant was in possession of the invention as it relates to functional variants.

Applicant respectfully disagrees with the Examiner's assertions regarding functional variants. The specification at pages 16-17 and 19-22 provides ample and specific description that conveys to one of ordinary skill in the art that Applicant was in possession of the claimed invention.

Nevertheless, in order to facilitate allowance of the application, Applicant has amended the claims to remove the references to functional variants. Accordingly, Applicant believes that the rejection is moot, and respectfully requests its withdrawal.

Enablement Rejection

The Examiner rejected claims 79 and 80 as not enabled by the specification. According to the Examiner, the basis for the rejection is that the specification does not describe how to make and use the claimed invention as it relates to functional variants.

Applicant respectfully disagrees with the Examiner's assertions regarding functional variants. The specification at pages 16-17 and 19-22 provides ample and specific description for making and using the claimed invention. Based on this description, and notwithstanding the articles cited by the Examiner, Applicant asserts that this aspect of the invention can be practiced based on the teachings in the specification, with only routine experimentation.

Nevertheless, as above for the written description rejection, in order to facilitate allowance of the application, Applicant has amended the claims to remove the references to functional variants. Accordingly, Applicant believes that the rejection is moot, and respectfully requests its withdrawal.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claim 80 as indefinite for lack of antecedent basis. Applicant has amended claim 80 to remove this limitation, thereby rendering this rejection moot. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

The Examiner rejected claims 8 and 79-85 under 35 U.S.C. 103(a) as unpatentable over US 6,667,037 in combination with a number of secondary references. Applicant respectfully traverses the rejection.

US 6,667,037 does disclose the peptide that the present specification refers to as SEQ ID NO:8, EADPTGHSY. However, this peptide is disclosed as one that is presented by HLA-A1, and not by any other HLA molecule, let alone HLA-B35. (In fact, none of the peptides listed in the table in column 6 are described as being presented by HLA-B35.) Further, US 6,667,037

does not disclose a method for stimulating an immune response in a HLA-B35 positive subject by administering to the subject a MAGE-A1 HLA-B35 binding peptide comprising SEQ ID NO:10 as is presently claimed.

US 6,667,037 does disclose that tyrosinase can be processed to produce a peptide that is presented by HLA-B35. However, this disclosure does not provide one of ordinary skill in the art with motivation to look at other proteins as encoding HLA-B35-presented peptides, particularly not MAGE-A1 specifically, with a view to identifying peptides useful in methods for inducing an immune response in HLA-B35 positive individuals. Further, the patent provides no expectation of success, because the peptide from tyrosinase has an entirely different sequence than the peptide used in the instant claimed methods.

In fact, US 6,667,037 teaches away from the present invention in Example 2, which is the Example in which the tyrosinase peptide was identified. In that Example, the applicants described testing several genes to determine if those genes encoded the peptide recognized by CTL 35-24. Among the genes were the MAGE genes; although it is not stated specifically that MAGE-A1 was screened, one of ordinary skill in the art would be left with the impression that MAGE-A1 was tested and that it did not encode the peptide presented by HLA-B35 and recognized by CTL 35-24. Therefore, Applicant strongly disagrees with the Examiner's statements on page 7 of the Office Action that one of ordinary skill in the art "would have realized that the MAGE-1 peptide might also bind to HLA-B53 [*sic*, B35]...." The theoretical possibility that one of the peptides in the many peptides listed in column 6 of US 6,667,037 would bind to HLA-35 is contradicted by the contrary experimental evidence supplied in Example 2 of US 6,667,037.

Regardless of the disclosure at column 6-7 cited by the Examiner (Office Action at page 6), administering peptides to HLA-B35-positive individuals to induce or increase an immune response implies the use of peptides that are presented by HLA-B35. US 6,667,037 does not provide a specific disclosure of peptides other than the tyrosinase peptide set forth as SEQ ID NO:1 in that patent.

Therefore, the teachings of US 6,667,037 would provide one of ordinary skill in the art with no motivation and, if anything, a negative expectation of success regarding finding a peptide in MAGE-A1 that is presented by HLA-B35. None of the other references cited by the Examiner remedies this lack of specific motivation and lack of an expectation of success. In

particular, the Celis reference cited by the Examiner in making the enablement rejection illustrates the point that there is not a reasonable expectation of success based on computer-based prediction of peptide epitopes absent experimental confirmation. In the present case, US 6,667,037 offers no indication that the EADPTGHSY sequence would be presented by any HLA molecule other than HLA-A1. None of the other references supply the missing motivation or elements missing from the instant claims.

Because neither US 6,667,037 nor any of the other cited references provides any motivation or expectation of success with respect to the presently claimed invention, the claims of this invention should not be considered unpatentable as obvious in view of US 6,667,037. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection based on the combination of US 6,667,037 with several other references.

Conclusion

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,


John R. Van Amsterdam, Reg. No. 40,212
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210
Telephone: (617) 720-3500

Docket No. L0461.70104US00
Date: December 21, 2004
x01/01/05